ROUTING OF NADA DECISION PACKAGE

1. Purpose:

   This guide describes the procedures for routing the NADA decision package to obtain necessary clearances and approvals. When the decision package moves between Divisions or into and out of the Quality Assurance Support Team (HFV-102) it is routed through the Document Control Unit HFV-199 enabling the Center to monitor movement of any decision package using the STARS system.

2. Routing of Incomplete NADA:

   If an application is incomplete, the primary reviewer sequentially routes the decision package as follows:

   a. Team Leader for review and concurrence on the letter to the firm;

   b. Division Director for review, concurrence and signature;

   c. Document Control Unit (HFV-199) for issuance.

3. Routing of Approvable Original NADA or ANADA:

   If the reviewer recommends approval of the NADA, the decision package, including the draft FEDERAL REGISTER document, is sequentially routed as follows:

   a. Team Leader for review and concurrence;

   b. Division Director for review and concurrence;

   c. If the approval involves a new or revised tolerance or withdrawal time for a drug used in food animals, the documents in Folder A (see f. below) are hand-carried to the Director, Division of Human Food Safety for review and concurrence. Upon review and concurrence Folder A is then hand-carried back to the review division. (Note: For expedience, this step is not controlled through Document Control).

d. Quality Assurance Support Team (HFV-102) for review and concurrence;

e. Director, NADE (HFV-100) for review and concurrence;

f. HFV-100 forwards Folder A, containing the draft letter, draft regulation, FOI Summary and labeling, Briefing Memo, and, if applicable, the FONSI, to the Office of Chief Counsel (GCF-1) for review and concurrence. The rest of the NADA file is returned to HFV-199.

g. GCF-1 sends the folder back to HFV-100 who forwards the "approved Draft Regulation" through HFV-6 to the Regulations Editorial Staff (HF-27) to be put into final format. The remaining parts of the package are returned to HFV-199. If revisions are needed in the FOI Summary or other documents HFV-102 will return the package to the review Division for revision and preparation of final copies.

h. The FPL letter, if needed, is signed by the Director, Office of New Animal Drug Evaluation and issued by HFV-199.

i. HF-27 returns the final regulation to HFV-6 (for tracking purposes) who forwards it to HFV-199.

If a letter requesting FPL has been sent, then routing in i,j,k, and l needs to be followed. If no FPL letter was needed, then the package is sent directly to HFV-102.

j. HFV-199 retains the final regulation until the FPL arrives from the applicant.

When it arrives, the FPL and the approval package are returned by HFV-199 to the reviewing branch. The review Team makes any necessary corrections and/or concurs in the corrections made by any of the review offices. If FPL is satisfactory, an approval letter is prepared for the Center Director's signature.

k. The Team Leader forwards the package to the Division Director for review and concurrence.

l. The Division Director forwards the package to the Quality Assurance Support Team (HFV-102) for review and concurrence.

m. HFV-102 forwards the package to HFV-100 for review and concurrence.

n. For an original NADA or a major supplement requiring the Center Director's signature, HFV-100 concurs by initialing the Briefing Memo, the salmon copy of the approval letter, the signature page of the FOI summary, and the blue routing sheet and the yellow copy of the final regulation. HFV-100 forwards the approval package through HFV-199 to HFV-1. HFV-1 signs the approval letter and the final regulation, initials the blue transmittal

sheet, pulls the HFV-2 and HFV-12 (FOI Officer) copies of the FOI summary and labeling, and returns the rest of the approval package to HFV-102.

o. For a supplement to be approved by HFV-100, HFV-100 signs the approval letter and the final regulation, initials and dates the blue routing sheet, and the final FOI summary. Then the package is hand carried to HFV-102.

p. For both types of approvals (those signed by HFV-1 and HFV-100), HFV-199 dates and places the approval letter and any attachments in the previously addressed envelope and puts the envelope in the U.S. mail; dates and signature stamps all copies of the letter; dates all copies of the FOI Summary and the Environmental documents the same date as the letter if approval is by letter; date stamps the final regulation with the date of the approval letter if approval is by letter; and hand carries the final FR document to HFV-102 who puts a note on it for HF-27 to notify HFV-102 when the date of publication has been certified, then hand carries it to HF-27 (Parklawn Building, Room 12A-19) for publication.

q. HFV-199 (or, alternatively, HFV-102) holds the HFA-305 copies of the FOI Summary, labeling, and environmental documents until HFV-102 is notified by HF-27 of the certified date of publication in the FEDERAL REGISTER. HFV-199 stamp dates the FOI Summary the same date as the certified date of publication if the approval is for a Category II Type A Medicated Article. Then HFV-102 hand carries the HFA-305 copies to HFA-305 for display.

HFV-199 also pulls and distributes copies of the approval letter, FOI Summary and Briefing Memo which are designated for HFV-100 and HFV-102 (Green Book). The rest of the file is held until the regulation is published in the FEDERAL REGISTER. A copy of the published regulation is added to the package and the entire file is sent to HFV-199 where the rest of the distribution is made, the approval package tracking form is completed, and the final action code entered into STARS, and the DCU FOI Summary file established.

r. HF-27 forwards a copy of the certified FEDERAL REGISTER document to HFA-305 (Park Building, Room 1-23, 12420 Parklawn Drive) for public display a day or two prior to publication.

s. Transfers between buildings (for example, Metro Park North II to Parklawn) of a decision package or package containing documents for HFA-305 (for Public Display) are made to ensure document control. Hence, such transfers are hand carried by CVM's courier, Office of Management and Communications, HFV-10, or other authorized personnel.